National Institutes of Health



January 15, 2009

Dr. Jerry Smrchek U.S. National Coordinator for the OECD Test Guidelines Program U.S. Environmental Protection Agency Ariel Rios Building, Mail Code 7403M 1200 Pennsylvania Avenue, NW Washington, DC 20460 National Institute of Environmental Health Sciences NTP Interagency Center for the Evaluation of Alternative Toxicological Methods P. O. Box 12233 Research Triangle Park, NC 27709 http://iccvam.niehs.nih.gov

Dear Dr. Smrchek:

On behalf of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and the ICCVAM Acute Toxicity Working Group, we are pleased to provide the attached comments on the proposed OECD acute inhalation package comprised of 1) the Draft Proposal for a Revised Guideline 403: Acute Inhalation Toxicity, 2) the Draft Proposal for a New Guideline 436: Acute Inhalation Toxicity - Acute Toxic Class (ATC) Method, and 3) the Draft Guidance Document No 39: Acute Inhalation Toxicity. These comments are in response to the November 28, 2008 notification from the OECD requesting comments on the proposed acute inhalation package.

We have included comments regarding suggested editorial revisions and corrections for each test guideline and the guidance document. Additionally, we have suggested modifications to the text to add specificity for the types of information that would support not conducting additional testing, or assist in the choice of the most appropriate species, strains, gender, and mode of exposure for the study as judged for highest usefulness and relevance for human risk assessment purposes.

We appreciate the opportunity for the ICCVAM to provide comments on the revised draft test guidelines and guidance document in the acute inhalation package. Please feel free to contact me at any time if you have questions or concerns regarding these comments.

Sincerely,

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William S. Stokes, D.V.M., D.A.C.L.A.M. Rear Admiral, U.S. Public Health Service Director, NTP Interagency Center for the Evaluation of Alternative Toxicological Methods National Institute of Environmental Health Sciences

Enclosure

cc:

ICCVAM Agency Representatives Acute Toxicity Working Group